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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,458	10/05/2000	Mary E. Gerritsen	10716-4 (P1776R2 and Cura	2273
26263	7590	11/20/2003	EXAMINER	
SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/684,458	Applicant(s) GERRITSEN ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

--Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

THE REPLY FILED 26 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 019-26-2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 24-35,60-63 and 67.

Claim(s) withdrawn from consideration: 1-23,36-59,64,65 and 68-112.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: Attachment

Gary B. Nickol

Advisory Action

The Amendment filed September 26, 2003 in response to Final Rejection mailed March 26, 2003 is acknowledged and has been entered.

Claims 1-65, 67-112 are pending in the application.

Claims 1-23, 36-59, 64-65, and 68-112 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 24-35, 60-63, and 67 are currently under prosecution.

Objections:

Claim 63 remains objected for the reasons of record with regards to recitation of “or antibody”.

Rejections:

Claims 24-35, 60-63, 67 remain rejected under 35 U.S.C. 112, first paragraph because one skilled in the art would not know how to use the claimed invention for the reasons of record.

Applicant's have argued that the specification teaches one of skill in the art how to use PRO-C-MG.2 (SEQ ID NO:2) to inhibit or promote angiogenesis, especially in light of PRO-C-MG.2's *structural* motifs, sequence homologies and expression pattern, as well as the state of the art at the time of filing. Applicant's further argue that because PRO-C-MG.2 expression is up-regulated during angiogenesis, and because it likely has phosphorylation activity, one of skill in the art would know how to use PRO-C-MG.2 to modulate the process of new blood vessel formation. For example, applicants argue that application of a kinase inhibitor would inactivate

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any phosphorylation activity by PRO-C-MG.2 while kinase activators would promote angiogenesis by stimulating PRO-C-MG.2 phosphorylation activity. Further, such inhibitors could be administered to sites of tumorigenesis to halt the growth of the tumor by interfering with vascularization, a prerequisite for tumor growth. Applicants argue that given the putative phosphorylation sites and definitive kinase domain, PRO-C-MG.2 is clearly involved in intracellular signaling. Adding the characteristics of a coiled-coil domain and nuclear localization, applicants further contend that it is almost certain that PRO-C-MG.2 is important in gene expression, either as a transcription factor, part of higher-order chromatin structure that affects gene expression, or other house-keeping-like function, such as RNA transport. These arguments have been carefully considered but are not found persuasive. Applicants have attempted to define the functional characteristics of a novel polypeptide based on known structural motifs; however, applicants have not shown a parallel between these regions and or domains with polypeptides that are known to be angiogenic and that also contain such domains. Hence, there is no nexus between the proposed biological activity of the protein and the putative sites of phosphorylation and or kinase activity. The results and teachings of the specification only give an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed polypeptide. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 24, 26, and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record.

Applicants argue that compliance with the written description does not require an applicant to describe exactly the subject matter claimed; rather the description must allow one of ordinary skill in the art to recognize that the applicant has invented what is claimed. Applicants argue that they have provided an adequate description of the claimed invention in the form of SEQ ID NO. Applicant's further point to the teachings of Bowie *et al.* (1990) to validate their argument that variant sequences can be made consistent with the teachings of the specification. These arguments have been carefully considered but are not found persuasive. The claims are drawn to polypeptides having at least 80% sequence identity with a particular disclosed sequence. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity. And, the fact that it would require further experimentation to those of skill in the art in order to produce the multitude of variant polypeptides as claimed does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Factors to be considered when determining whether or not the claimed invention meets the written description guidelines generally include the disclosure of complete or partial structures, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. Accordingly, in the absence of sufficient recitation of

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distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
November 17, 2003

